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EXHIBIT # 1

510(K) SUMMARY

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR §807.92.

The assigned 510(k) number is: K040002

1. Submitter's Identification:

Microlife Intellectual Property GmbH, Switzerland
Max Schmidheiny-Strasse 201
9435 Heerbrugg / Switzerland

Date Summary Prepared: December 30, 2003

Contact: Mr. Gerhard Frick

2. Name of the Device:

Microlife Blood Pressure Monitor Model BP3AX1

3. Predicate Device Information:

The Microlife Wrist Watch Automatic Blood Pressure Monitor, Models BP3AX1 is substantially equivalent to the Microlife Automatic Blood Pressure Monitor, Model BP-3BU1-5, K# 021305.

4. Device Description:

The Microlife Wrist Watch Blood Pressure Monitor BP3AX1 is designed to measure the systolic, diastolic and pulse rate of an individual by using a non-invasive technique with an inflatable cuff wrapped around wrist. Our method to define systolic and diastolic pressures is similar to the auscultatory method but uses an electronic semiconductor pressure sensor rather than stethoscope and mercury manometer. The sensor converts tiny alteration in cuff pressure to electrical signals; by analyzing those signals to define the systolic, diastolic and calculating pulse rate is a well known technique in the market and is the so called "oscillometric method".

5. Intended Use:

The Microlife Wrist Watch Blood Pressure Monitor, Model BP3AX1 is a device intended to measure the systolic and diastolic blood pressure and pulse rate of an adult individual by using a non-invasive technique in which an inflatable cuff is wrapped around the wrist.

6. Comparison to Predicate Devices:

All devices use the well known oscillometric method within the software algorithm to determine the systolic and diastolic blood pressure and pulse rate. A wrist inflatable cuff is inflated automatically; deflate rate is controlled by one linear valve and the deflation pressures are transferred via tubing to a sensor in all units. But our new model BP3AX1 uses semiconductor pressure sensor instead of capacitive pressure sensor on the predicate device to translate the pressure variations to electrical signals that can be interpreted by an integrating circuit. Once the reading is determined each unit operates the linear valve to release the pressure to zero.

Unlike the predicate device, our new model BP3AX1 uses a piezo-resitive pressure sensor to detect alternation of cuff pressure. The basic theory of the sensor is stated below:

The diffusion-type semiconductor pressure sensor has four pressure senitive elements or piezo resistors which are formed on the diaphragm surface of silicon chip substrate by a conventional diffusion process of IC production technique.

The piezo resistors change those resistivity by applied stress called as piezo resistance effect when the diaphragm is formed by the applied pressure.

The resistivity change of the four resisters which consist of the wheatstone brige circuit induce a pressure proportional bridge output voltage by a externally supplied driving current or voltage.

$$V \propto P$$

Where V is the sensor output voltage
P is the applied pressure

In addition in our pressure monitor, we have deleted the printer function.

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7. **Discussion of Non-Clinical Tests Performed for Determination of Substantial Equivalence are as follows:**

Testing information demonstrating safety and effectiveness of the Microlife Automatic Blood Pressure Monitor, Model BP3AX1 in the intended environment of use is supported by testing that was conducted in accordance with the FDA November 1993 Draft "Reviewer Guidance for Premarket Notification Submissions", DCRND, which outlines Electrical, Mechanical and Environmental Performance Requirements.

The following testing was conducted:

a. General Functions Test
b. Reliability Test - Operation Conditions
c. Reliability Test - Drop Testing
d. Reliability Test - Storage
e. Reliability Test - Vibrating Testing
f. EMC Test
g. IEC 60601-1 Safety Test

None of the testing demonstrated any design characteristics that violated the requirements of the Reviewer Guidance or resulted in any safety hazards. It was our conclusion that the Microlife Automatic Blood Pressure Monitor, Model BP3AX1 tested met all relevant requirements of the aforementioned tests.

8. **Discussion of Clinical Tests Performed:**

ANSI/AAMI SP10-1992 "National Standard for Electronic or Automated Sphygmomanometers" testing was performed. All relevant sections were addressed and testing conducted. The BP3AX1 met all relevant requirements of this standard.

9. **Conclusions:**

We have demonstrated that the Microlife Automatic Blood Pressure Monitor, Models BP3AX1, is as safe and effective as the predicate, the Microlife Automatic Blood Pressure Monitor, Model BP-3BU1-5 based on electrical, mechanical and environmental testing results as well as the FDA DCRND November 1993 Draft "Reviewer Guidance for Premarket Notification Submissions", and, the ANSI/AAMI Voluntary Standard, SP10-1992 testing results.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 2 2 2004

Microlife Intellectual Property GmbH
c/o Ms. Susan D. Goldstein-Falk
MDI Consultants, Inc.
55 Northern Blvd., Suite 200
Great Neck, NY 11021

Re: K040002
Microlife Wrist Watch Blood Pressure Monitor, Model BP3AX1
Regulation Number: 21 CFR 870.1130
Regulation Name: Noninvasive Blood Pressure Measurement System
Regulatory Class: Class II (two)
Product Code: DXN
Dated: December 30, 2003
Received: January 2, 2004

Dear Ms. Goldstein-Falk:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act

or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4646. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97) you may obtain. Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Donna R. Lochner

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Exhibit B

510(k) Number (if known): K040002

Device Name: Microlife Wrist Watch Blood Pressure Monitor, Model BP3AX1

Indications For Use:

The Microlife Wrist Watch Blood Pressure Monitor, Model BP3AX1 is a device intended to measure the systolic and diastolic blood pressure and pulse rate of an adult individual by using a non-invasive technique in which an inflatable cuff is wrapped around the wrist.

Prescription Use _____ **(Per 21 CFR 801 Subpart D)**	**OR**	**Over-The Counter Use** _X_ **(21 CFT 807 Subpart C)**

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Donna R. Lachman

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K040002